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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,571	08/20/2003	Robert Hugh McKenna	END-5106 -515143	6638
26874 7590 02/01/2007 FROST BROWN TODD, LLC 2200 PNC CENTER 201 E. FIFTH STREET CINCINNATI, OH 45202			EXAMINER ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/644,571	<b>Applicant(s)</b> MCKENNA ET AL.	
	<b>Examiner</b> DAVID J. ISABELLA	<b>Art Unit</b> 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 11-14, 16, 17 and 20-43 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 11-14, 16, 17 and 26-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Status of the Claims***

Claims 2-10,15,18-19 have been cancelled. Claims 20-25 have been withdrawn. Claims 26-43 have been newly added.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,11-14,16-17,26-43 are rejected under 35 U.S.C. 102(e) as being anticipated by any of Levine (2004/0249312 or 2004/0220682), Stack et al (2003/0040804) or Kagan et al (2004/0092892).

Applicant's remarks as filed indicates that a declaration under 37 C.F.R. 1.131 swearing behind the Levine applications was filed concurrently with applicant's response. However, no such declaration was recorded or indicated to be received by the Office. Therefor, the rejection under Levine is maintained.

Each of Levine, Stack, et al and Kagan et al disclose:

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an apparatus for diverting digestive secretions, the apparatus comprising a tube

a) a proximal end which when deployed is operative to receive digestive secretions,

b) a distal end which when deployed is operative to discharge the digestive secretions, and

c) a tube wall having an inner surface and an outer surface, the tube wall inner surface defining passage extending between the proximal and distal ends, wherein when deployed the passage is operative to transfer the digestive secretions from the proximal end to the distal end.

Claims 11 and 12, see permeability characteristics as disclosed by Levine, see paragraphs [0037] and [0064]; Stack et al [0038-0040]; Kagan et al [0018-0021]&[0241-0244].

Claim 13, since there is limited permeability in the devices of Levine, the tube inherently exhibits an osmotic gradient. See paragraph [0234-0236] of Kagan et al.

Claim 14, see rejection to claim 1 supra.

Claims 16-17, see rejections to claims 5-8 supra. Each device of Levine, Stack et al and Kagan et al, respectively, has a predetermined length.

Claims 26, see rejection to claim 1 supra. Claim 26 is broader in scope than claim 1, in that, the claim does not require an anchor.

Claims 27-30, see stents 360,460,560 of Levine '682 and 216 of Levine '362; Kagan et al 892 and Stack et al '804. With respect to the language of the claims directed to "attachment to various anatomical lumen" is not part of the "apparatus" as

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the anatomical lumen is more appropriately directed to a method for providing a fluid channel for moving secretion. Therefor, the limitations of the ampulla, bile duct, pancreatic duct, duodenum, duodenal papilla, jejunum and ileum fails to positively further limit the structure of the apparatus as claimed.

Claims 32-36,39-43, see paragraphs [0062-0064] of Levine; [0236-0244] of Kagan et al; and [0038-0054] of Stack et al.

Claim 37, see paragraph [0043] of Stack et al.

Claims 31 and 38, see paragraph [0319] of Kagan et al.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,11,12,13,14,16-17,26-36,38-43 are rejected under 35 U.S.C. 102(b) as being anticipate by Ryan et al (6576009).

Ryan et discloses :

an apparatus comprising a tube a) a proximal end which when deployed in a lumen,

b) a distal end, and

c) a tube wall having an inner surface and an outer surface, the tube wall inner surface defining passage extending between the proximal and distal ends, wherein when deployed the passage is operative to transfer fluid from the proximal end to the distal end.

The manner in which the device is placed *invivo* is directed to an intended use of the device and does not inherently further limit the same. Moreover, the limitations of bile or pancreatic secretion fails to positively further limit the structure of the apparatus as claimed. As broadly claimed, the apparatus is a tube that allows fluid to flow from one end thereof out of the second end thereof.

Claims 11 and 12, see permeability characteristics as disclosed by Ryan et al.

Claim 13, since there is limited permeability in the devices of Ryan et al, the tube inherently exhibits an osmotic gradient.

Claim 14, see rejection to claim 1 *supra*.

Claims 16-17, the device of Ryan et al has a predetermined length.

Claims 26-36 and 38-43, see columns 3-6 of Ryan et al.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
3/14/2006